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EPA

Chemical Right to Know
High Production Volume Challenge Program
Fact Sheet on Animal Welfare

The HPV Challenge Program

The goal of the HPV Challenge Program is to ensure that a baseline set of environmental and health effects data on approximately 2,800 high production volume (HPV) chemicals is made available to EPA and the public. EPA believes that the availability of this information is vitally important so that the public can better understand chemical hazards in their communities, homes, and workplaces, and so that EPA can make sound decisions about priorities for possible future regulation and take appropriate risk management actions if necessary.

U.S. manufacturers and importers are voluntarily providing basic human health and environmental effects data for their HPV chemicals; i.e., those produced or imported into the U.S. in volumes of 1 million pounds or more per year. These data comprise the HPV Screening Information Data Set (SIDS), developed by the Organization for Economic Cooperation and Development (OECD). EPA intends to consider specific chemicals which are not voluntarily sponsored as candidates for test rules under Section 4 of the Toxic Substances Control Act. Sponsorship entails identifying existing information and assessing its adequacy, conducting new testing only if adequate information does not exist, and providing the new and existing data to EPA. EPA is making this information accessible to the public.

The Role of Existing Data

EPA believes that it is important to achieve the goals of the HPV Challenge Program in a manner that takes into account animal welfare concerns. As a result, this Program has been designed from the start to encourage companies to consider approaches that can reduce the amount of testing needed and avoid duplicative testing. EPA encourages industry and others to search for relevant and scientifically valid existing data, and to share that information with EPA and the public. Companies have the opportunity to submit plans for testing chemical categories, which involves collecting data on a subset of chemicals considered to be representative of an entire class or group of chemicals. Chemicals for which adequate SIDS data exist are not retested under the HPV Challenge Program or any associated test rule(s) that are limited to SIDS testing. All test plans submitted by sponsors under the HPV Challenge Program are posted on the Internet for a 120-day review period prior to the start of testing. This provides an opportunity for identifying scientifically valid existing data which may not have been cited and for recommending revisions to the test plans which could reduce the need for additional animal testing.

Efforts to Reduce Animal Testing

EPA is committed to examining alternative test methods that reduce the number of animals needed for testing, reduce pain and suffering of test animals, and whenever possible, replace animals in testing with validated *in vitro* (non-animal) test systems. EPA has released guidance on this issue to companies participating in the HPV Challenge Program.

This guidance promotes the maximum use of existing data, and encourages companies to disclose existing data not previously made publicly available. The guidance also states that sponsors are encouraged to defer certain animal tests and use certain in vitro tests to address endpoints for which adequate existing data are not available. EPA recommends delaying some necessary testing of individual chemicals until November 2001, and testing of closed system intermediates, which present less risk of exposure, until 2003. Federal funds have also been committed to the evaluation of alternative test methods.

EPA has taken several important steps to address animal welfare issues in the HPV Challenge Program. EPA recommends the use of an alternative to the standard LD50 test that reduces the number of rodents needed by 60 percent. EPA has reevaluated its preference for the rodent genetic toxicity test and encourages the use of non-animal alternatives. EPA also recommends the use of combined studies and specific actions to reduce pain and distress in test animals. Taken together, the measures which EPA has recommended would reduce animal usage by 68 to 80 percent. EPA has communicated these testing recommendations to sponsors of HPV chemicals.

For more information on the specific actions EPA is taking to reduce the use of animals in the HPV Challenge Program, or general information about the Chemical Right-to-Know Initiative, please visit our web site at *http://www.epa.gov/chemrtk* or call (202) 260-3951. Interested stakeholders may join our automated updated notification service on the "What's New" page to receive email updates on the HPV Program. All documents posted on the website may be obtained in hard copy by contacting the TSCA Assistance Information Service at (202) 554-1404.

Types and Validity of Data to be Collected

The OECD HPV SIDS data set represents an internationally agreed upon set of studies needed to screen HPV chemicals and identify potential hazards. These include studies for physical chemical properties (e.g., water solubility), environmental fate (e.g., biodegradation), environmental toxicity to fish and other aquatic species, and mammalian toxicity (acute toxicity, genetic toxicity, repeat dose toxicity, and reproductive and developmental toxicity). The SIDS data set does not include the developmental neurotoxicity test (DNT). Consequently, the DNT is <u>not</u> part of the HPV Challenge Program. Any needed testing under the this Program is to be conducted using test guidelines which are recognized and accepted by governments and scientists worldwide as providing high quality, screening level data.

Scientific Validation of Alternative Non-Animal Testing

Scientific validation is an essential step in determining the adequacy of new alternative test methods. Scientific peer review to determine the level of validation of alternative protocols is performed by various recognized authorities such as the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), of which EPA is a member. Following the recommendations of such organizations, federal agencies then decide whether to adopt alternative test methods for their regulatory purposes.

Until non-animal test methods are validated and achieve regulatory acceptance, these methods cannot be relied on as alternatives to established test guideline studies for purposes of the HPV Challenge Program or any associated test rule(s). EPA is working with other federal agencies to identify, validate, and peer review potential alternative protocols, and to ensure the scientific and regulatory acceptability of the tests. ICCVAM recently initiated a process to investigate the potential for validation of various acute *in vitro* methods, including the Multi-center Evaluation of In Vitro Cytotoxicity (MEIC) battery of tests. These in vitro tests are being evaluated as possible alternatives to or supplements for animal tests for acute toxicity. EPA and ICCVAM co-sponsored a workshop in October 2000, on in vitro methods for acute toxicity. The recommendations of that workshop will be used to consider validation of the most promising methods. As relevant alternative test methods become validated and achieve regulatory acceptance during the implementation of the HPV Challenge Program, EPA will consider their immediate implementation in the Program. To enhance the use of alternative testing methods, EPA will continue to involve animal welfare interest groups and other interested parties in a constructive dialogue to identify and develop such methods.